

Residual Bacteria Burden at Surgical Closure

How intraoperative lavage strategies are evaluated

This brief summarizes independent evidence evaluating bacterial reduction achieved by intraoperative lavage strategies at surgical closure.

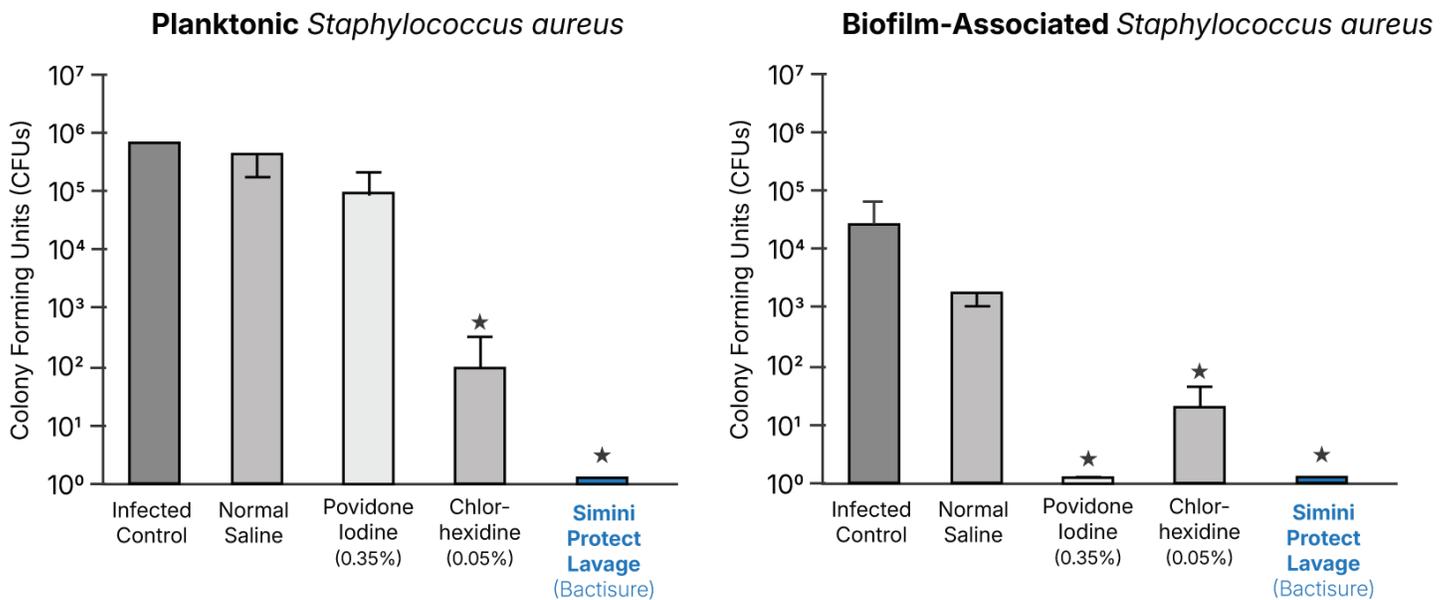


Figure 1. Representative comparison of residual bacterial recovery measured immediately following exposure to intraoperative lavages under identical conditions. Data adapted from Hamad et al., Journal of Bone and Joint Surgery, 2025.

At a glance

How intraoperative lavage strategies are evaluated

Endpoint: Residual bacteria burden at closure

Comparator: Saline under identical conditions

Models: In vitro, implant-associated, biofilm-associated, in-vivo surgical models

Clinical Role: Adjunct to standard intraoperative lavage in veterinary orthopedic surgery

Intraoperative lavage strategies are evaluated using controlled, head-to-head microbiologic methods designed to isolate the effect of the lavage itself.³⁻⁴

- ✓ Defined bacterial inoculation
- ✓ Standardized lavage protocols
- ✓ Quantitative microbiologic recovery
- ✓ Direct comparison between lavage strategies under identical conditions



By focusing on measurable activity-based endpoints at closure, this framework allows meaningful comparison of intraoperative lavage approaches without reliance on clinical outcomes influenced by external variables.

What Different Study Designs Evaluate

Randomized Clinical Trials: Assessing Clinical Outcomes

Randomized clinical trials (RCTs) are designed to assess whether an intervention alters clinical outcomes, such as surgical site infection rates, across diverse patients, procedures, environments, and postoperative courses.

Because **surgical site infection** is a relatively infrequent event and is influenced by numerous factors beyond the operating field, RCTs evaluating infection rates inherently reflect the combined effects of multiple variables, including:¹⁻²

- Host immune status and comorbidities
- Surgical complexity, duration, and tissue handling
- Environmental and institutional factors
- Postoperative wound care and antimicrobial use
- Variability in surgical technique and protocol adherence

RCTs are well suited for evaluating **population-level outcomes**, but *less suited for isolate specific intraoperative effects*.

Activity-Based Studies: Evaluating Intraoperative Effects

Activity-based studies focus on measurable intraoperative endpoints, such as residual bacterial burden at the time of surgical closure.³⁻⁵

- Standardized inoculation and lavage
- Quantitative microbiological comparison under controlled conditions

RCTs Ask:

*Does this **intervention** change infection rates across heterogenous patients and care environments?*

Activity-Based Studies Ask:

*Does this **intervention** reduce bacterial burden under controlled intraoperative conditions?*

RCTs assess downstream clinical outcomes influenced by multiple factors.

Activity-based studies isolate measurable intraoperative effects at the time of closure.

Variability in Infection Rate Outcomes

Why mixed results are expected in *surgical site infection trials*

Randomized and comparative studies evaluating surgical site infection (SSI) prevention strategies frequently report mixed or inconsistent results, even when assessing similar procedures or interventions over extended periods of time.¹⁻²

- **Low baseline incidence** in most surgical populations
- **Multifactorial causation** including host, procedural, **environmental**, and postoperative influences
- **Downstream timing**, with infections occurring days to weeks after surgical closure
- Sensitivity to protocol variation, adherence, and institutional practices

Variability in Surgical Site Infection Prevention Studies Over Time

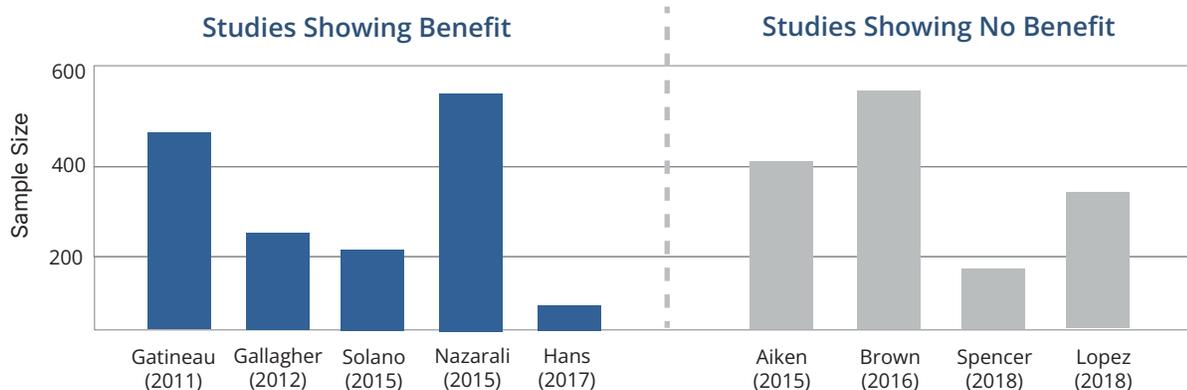


Figure 1. Variability in Surgical Site Infection Prevention Studies Over Time. Representative summary of published studies evaluating post-surgical-prophylactic antibiotics to reduce surgical site infections from 2011-2020, illustrating mixed infection-rate outcomes despite biologically plausible interventions. Variability reflects the low incidence of SSI and the influence of multiple host, procedural, environmental, and postoperative factors beyond direct intraoperative control.

Interpretation of infection-rate trial heterogeneity

- **Importantly**, mixed findings across infection-prevention trials should not be interpreted as evidence that intraoperative interventions lack activity.¹⁻²
- Illustrate the challenge of detecting differences in rare, multifactorial outcomes using population-level endpoints
- Do not negate the importance of activity-based evaluations isolating measurable intraoperative effects.

Comparison With Saline Under Controlled Conditions

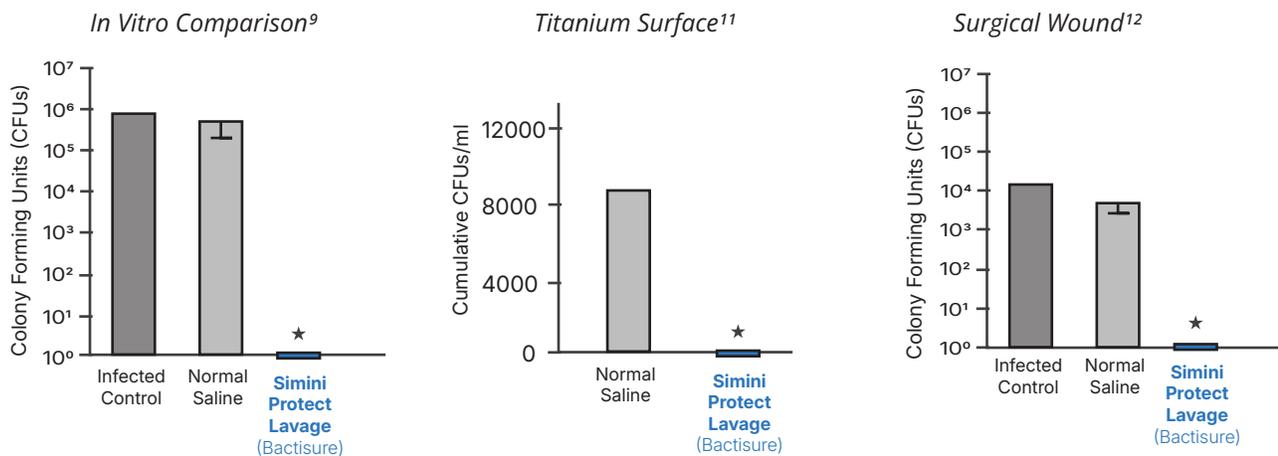
In comparative laboratory and surgical models, Simini Protect Lavage has been evaluated alongside saline using standardized protocols designed to isolate intraoperative activity under surgical control.⁸⁻¹²

Across these studies, experimental conditions typically include:

- Defined bacterial inoculation of surgical wounds or implant-relevant surfaces
- Standardized lavage volumes, exposure times, and delivery methods
- Immediate quantitative microbiologic recovery at the time of closure
- Direct comparison of recoverable bacterial burden between lavage strategies

This design ensures that observed differences reflect the activity of the lavage solution itself, rather than variability in surgical technique, wound management, or postoperative factors.

Planktonic *Staphylococcus aureus*



Findings Across Controlled Models

Across multiple independent evaluations, Simini Protect Lavage has demonstrated lower recoverable bacterial burden at closure compared to saline when assessed under identical experimental conditions.⁸⁻¹²

Clinical Relevance

By isolating intraoperative activity and measuring residual bacterial burden at the time of closure, this evidence framework directly evaluates the performance of lavage solutions under surgical control.

Within this context, the consistent reduction in recoverable bacterial burden observed with Simini Protect Lavage supports its consideration as an adjunct to standard saline irrigation in veterinary orthopedic surgery.

Biofilm Conditions and Activity in Revision Surgery Contexts

Activity Against Biofilm-Associated Bacteria Under Controlled Conditions

Biofilm-associated bacteria represent a distinct intraoperative challenge due to their adherence to implant surfaces and reduced susceptibility to antimicrobial agents.⁶⁻⁷

In controlled in vitro models designed to simulate implant-associated biofilm conditions, Simini Protect Lavage has been evaluated using quantitative, activity-based endpoints measuring residual recoverable bacterial burden following lavage exposure.

In the study by Kia et al. (*Journal of Shoulder and Elbow Surgery*, 2021), Simini Protect Lavage demonstrated lower residual recoverable bacterial burden across multiple clinically relevant organisms compared with dilute povidone-iodine (0.35%) and chlorhexidine (0.05%) when assessed under standardized biofilm conditions.¹⁰

Clinical Context: Use in Revision Procedures Where Biofilm Is Suspected

Revision orthopedic procedures represent clinical scenarios in which implant-associated biofilm is frequently suspected but difficult to directly measure intraoperatively.

While activity-based studies isolate intraoperative effects under controlled conditions, clinical case series provide contextual information regarding real-world use, safety, and feasibility in complex surgical environments.

In a retrospective case series reported by Forzisi et al. (*VCOT Open*, 2025), Simini Protect Lavage was incorporated as an adjunct to a multi-modal antiseptic protocol during total hip replacement revision surgeries. The study did not include a control group and was not designed to isolate the independent effect of lavage on infection outcomes.

Across 36 revision cases with a minimum one-year follow-up, most patients demonstrated no subsequent clinical or radiographic signs of infection, with one case requiring explantation following multiple prior revisions.¹⁴

Taken together, activity-based biofilm models and clinical revision case series address complementary questions. Controlled studies isolate intraoperative bacterial removal under defined conditions, while clinical observations provide context for how such technologies are incorporated into complex revision workflows.

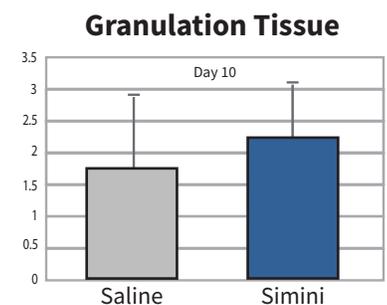
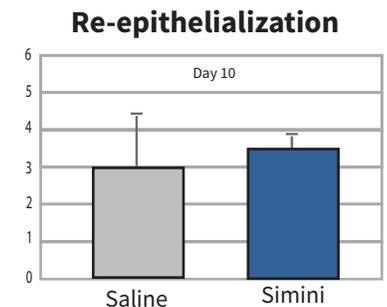
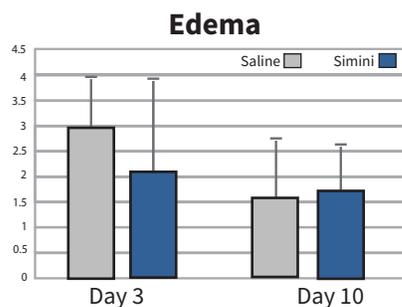
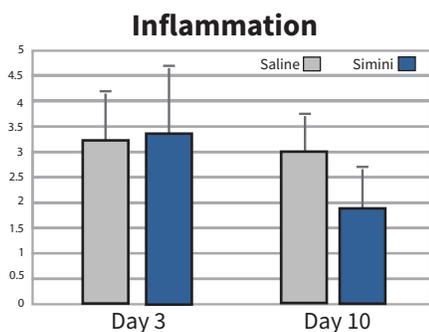
Safety and Tissue Compatibility Under Intraoperative Conditions

Intraoperative irrigation solutions are applied directly to exposed tissue and implant surfaces at the time of closure. In addition to bacterial reduction, surgeons must consider the potential effects of these agents on host tissue response and wound healing.

Histologic Evaluation of Host Tissue Response Following Short-Duration Exposure

Powell et al. evaluated the effects of commercially available irrigation solutions, including Bactisure (identical in formulation to Simini Protect Lavage), on uninfected host tissue using a murine full-thickness wound model. The study was designed to assess histologic markers of inflammation and wound healing following single, short-duration exposure consistent with intraoperative use.

At 3 days, wounds treated with Simini Protect Lavage demonstrated inflammatory and edematous responses consistent with normal acute wound healing. By 10 days, inflammation and edema had improved, and Simini Protect Lavage did not demonstrate delayed or impaired wound healing compared with saline controls.¹³



These findings support the conclusion that, when used as a single, short-duration intraoperative adjunct and followed by saline rinse, Simini Protect Lavage does not demonstrate greater tissue toxicity or impaired healing compared with saline alone in a non-infected setting.

Additional biocompatibility assessments, including ISO intramuscular implantation and porcine dermal models, further support tissue compatibility when used as intended.

Where Simini Protect Lavage Fits in Intraoperative Infection Control

Intraoperative infection-control strategies address a specific window of risk: the period between implant placement and wound closure.² Technologies applied during this window can be evaluated based on their direct intraoperative activity.¹

Within this framework, Simini Protect Lavage functions as a non-antibiotic intraoperative adjunct designed to reduce recoverable bacterial burden at the time of surgical closure.

It does not replace systemic antibiotics, sterile technique, or postoperative infection prevention measures, nor is it intended to independently determine clinical infection outcomes.

Intraoperative lavage strategies are applied in every surgical case to reduce residual bacterial burden prior to closure, regardless of perceived infection risk.

Simini Protect Lavage is best understood as an intraoperative tool whose performance is assessed at the time of application, based on its ability to reduce residual bacterial burden at surgical closure.

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